UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
BROWNSVILLE DIVISION

UNITED STATES OF AMERICA and STATE OF TEXAS *ex rel.* DR. JOSE G. DONES, Plaintiffs, v. HARLINGEN MEDICAL CENTER L.P., DR. ERIC G. SIX, VALLEY NEUROSURGEONS P.L.L.C., MICHAEL GONZALES, NUERA MEDICAL L.L.C., and PRIME HEALTHCARE SERVICES, INC. Defendants.	Case No. 1:21-cv-181

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS HARLINGEN MEDICAL CENTER L.P. AND PRIME HEALTHCARE SERVICES, INC.'S MOTION TO DISMISS RELATOR'S FIRST AMENDED COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

STATEMENT OF THE ISSUES

1. Is Prime Health Services, Inc. ("PHSI") a proper defendant in this action?

2. Has Relator pled sufficient allegations of violations of the False Claims Act, Texas Medicaid Fraud Prevention Act, Stark Law, and Anti-Kickback Statute under the plausibility standard of Federal Rule of Civil Procedure 8(a) and the more stringent particularity standard required for claims sounding in fraud under Federal Rule of Civil Procedure 9(b) against Harlingen Medical Center L.P. ("HMC") and PHSI?

3. Under Federal Rule of Civil Procedure 12(b)(6), does Relator fail to state a claim for violating the False Claims Act, Stark Law, Anti-Kickback Statute, and the Texas Medicaid Fraud Prevention Act against Prime Healthcare Services, Inc. and Harlingen Medical Center L.P.?

STANDARD OF REVIEW

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (citations omitted). The complaint must plead facts that "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "[B]lanket assertion[s] of entitlement to relief" are insufficient, as are labels, conclusions, and formulaic recitations of the elements of a cause of action. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 & n.3 (2007). Conclusory allegations or allegations that are no more than a statement of a legal conclusion "are not entitled to the assumption of truth." *Id.* at 679. In fact, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.* (quoting *Twombly*,

550 U.S., at 555). And a complaint that only "tenders 'naked assertion[s]' devoid of 'further factual enhancement'" likewise fails to suffice. *Id.* (quoting *Twombly*, 550 U.S. at 557).

Rule 9(b) requires that claims sounding in fraud, including False Claims Act allegations, be plead with particularity. *See U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009). "At a minimum" this requires the plaintiff to "plead the 'who, what, when, where, and how' of the alleged fraud." *U.S. ex rel. Colquitt v. Abbott Lab'ys*, 858 F.3d 365, 371 (5th Cir. 2017) (citation omitted). The Fifth Circuit applies Rule 9(b) "to fraud complaints with 'bite' and 'without apology'" because Rule 9(b) serves an important screening function to stand as a "gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009).

SUMMARY OF ARGUMENT

Relator Dones's First Amended Complaint (the "FAC") is precisely the type of complaint that Rule 9(b) is intended to prevent. As a threshold matter, Relator alleges no facts implicating PHSI other than that it owns HMC. This is insufficient to establish liability, and all claims against PHSI should be dismissed. Relator alleges HMC and PHSI and the other co-Defendants violated the False Claims Act ("FCA"), Texas Medicaid Fraud Prevention Act ("TMFPA"), Stark Law, and Anti-Kickback Statute ("AKS") through HMC's purchase of spinal equipment from NuERA and Xspine/Xtant. Relator argues that these purchases violate the above-mentioned state and federal laws because the son-in-law (Michael Gonzalez) of a physician who performs surgeries at HMC (Dr. Six) has some financial interest in or relationship with the companies. However, Relator has pled no fact or allegation to demonstrate that the HMC's business dealings with NuERA and Xspine/Xtant were anything more than proper business relationships. Relator also has not pled that any referral scheme existed, or that any improper payments were made from HMC or PHSI to

Dr. Six or Mr. Gonzales. Instead, Relator relies on labels and conclusions, unsupported by the facts alleged in the FAC. This is insufficient to survive a motion to dismiss under 9(b) and 12(b)(6).

The Court should dismiss the FCA and TMFPA claims, including those premised on violations of the Stark Law and AKS, for failure to plead specific allegations of fraud as required by Federal Rule of Civil Procedure 9(b). As its name suggests, the submission of a *false claim* is an essential element of a False Claims Act violation; a complaint that fails to plead examples of false claim submissions does not satisfy Rule 9(b). Relator pleads no fact of any allegedly false claim billed to a federal healthcare program and no indicia of reliability to support the inference that such claims were likely as required by the Fifth Circuit. The FAC also fails to allege an underlying scheme with sufficient detail. For example, Relator identifies no employee or representative of the HMC or PHSI by name or even position who was involved with the alleged scheme and fails to identify the relevant time frame the scheme occurred with any specificity, instead making general reference to a ten-year time frame dating back to 2012. Additionally, the FAC fails to allege any specific remuneration paid by the HMC or PHSI to Dr. Six or that any referral took place or resulted from any remuneration in violation of the AKS.

The elements of a Stark Law violation are also not adequately pled. The majority of prima facie elements of an FCA claim based on the Stark Law are not pled, including notably the failure to plead a prohibited financial relationship. The FAC also ignores a critical aspect of pleading an alleged conspiracy—a meeting or circumstance through which any alleged conspiracy was formed or executed. Moreover, Relator pleads no detail to separately support a violation of the TMFPA. Relator has no independent information and leave to amend the FAC would be futile. The court should dismiss the FAC with prejudice.

PROCEDURAL AND FACTUAL BACKGROUND

A. Nature of the Proceedings

Relator Dones filed a *qui tam* complaint under seal on November 17, 2021. (Dkt. No. 1). On January 23, 2023, the United States declined to intervene, and shortly thereafter on January 25, 2023, Texas declined to intervene. (Dkt. No. 13-14). Relator filed this First Amended Complaint on March 27, 2023. (Dkt. No. 18). PHSI and HMC now bring this response to the First Amended Complaint and seek dismissal of all Counts pled against them under Rules 12(b)(6) and 9(b).

B. The Parties

i. ***Harlingen Medical Center, L.P.*** is a level-four trauma designated hospital located in Harlingen, Texas. Dkt. No 18, Relator's First Amended Complaint ("FAC") ¶ 9.

ii. ***Prime Health Services, Inc.*** is alleged to be the sole general partner of HMC. FAC ¶ 10.[1]

iii. ***Relator Dones*** is a neurosurgeon who practices in the Rio Grande Valley. FAC ¶ 3. Relator Dones does not plead that he was ever an employee of HMC, that he has ever been involved in HMC's billing or supply chain processes, or that he was privy to any inside information regarding actual claims submitted by the hospital. He alleges no inside information regarding HMC's medical device procurement processes.

C. Allegations in the Complaint

At its core, the FAC alleges that the Relator's competitor and practicing neurosurgeon, Dr. Six, and HMC entered into a business arrangement violating the Stark Law and AKS. Relator alleges that the business arrangement, whereby HMC purchased spinal equipment from the

[1] This allegation is not correct. PHSI is not the sole general partner of HMC, but we assume the statement as pled for purposes of a motion to dismiss.

companies NuERA and Xspine/Xtant at Dr. Six's request, was improper because Dr. Six's son-in-law had a financial interest in or financial relationship with the medical device distributor companies. Relator also alleges that by allowing Dr. Six to influence the distributors from which HMC purchased medical devices used in Dr Six's surgeries, HMC violated the FCA and TMFPA. The unspecified time period offered by Relator for his allegations is "since at least 2012." *Id.* ¶¶ 55, 59.

The Complaint alleges violations of the FCA under 31 U.S.C § 3729(a)(1)(A) ("presenting false claims") and 31 U.S.C § 3729(a)(1)(B) ("making or using false records or statements"), conspiracy to violate the FCA under 31 U.S.C. §3729(a)(1)(C), two counts of violating the TMFPA under Tex. Human Res. Code Ann. §§ 36.002(1), (4)(B) and conspiracy to violate the TMFPA under § 36.002(9). The Complaint alleges that violations of the FCA and TMFPA arise from violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and the Stark Law, 42 U.S.C. § 1395nn.

Specifically, the Complaint alleges that Dr. Six's son-in-law, Michael Gonzales, sells and distributes medical devices for surgeries, including neurosurgery, through his company, NuERA Medical. *Id.* ¶¶ 7-8. Mr. Gonzales is also alleged to act as a representative and receive commissions for companies Xspine/Xtant. *Id.* ¶¶ 46, 50, 67. Relator alleges that Dr. Six asked HMC to purchase medical devices from NuERA and Xspine/Xtant for his surgeries and that HMC agreed to allow Dr. Six to use the medical devices he wanted for surgeries as a reward for performing the surgeries at HMC. *Id.* ¶¶ 46-48. The FAC alleges that surgeries performed by Dr. Six at HMC bring revenue to HMC, and to PHSI, as a result of owning HMC. *Id.* ¶ 46. These allegations do not allege anything beyond the ordinary course of business. The FAC does not provide any factual explanation of how HMC allowing Dr. Six to use his preferred medical devices

from NuERA or Xspine/Xtant in surgeries he performed constituted an improper financial benefit. There is no explanation for how this business relationship constituted a prohibited referral or wrongful payment scheme, and no fact is offered to explain any supposed agreement for the benefit of HMC or Dr. Six beyond an ordinary business relationship in which a physician performs surgeries with his or her preferred medical devices. The FAC lacks any factual support to explain knowledge by HMC or PHSI, instead offering only conclusions. *See id.* ¶ 50 (offering conclusions but no factual support to explain the basis of knowledge or violation, "HMC, PHS . . . all knew that Gonzales was Dr. Six's son-in-law, and that it was a Stark violation . . . "); *id.* ¶ 54 (offering conclusion but no factual explanation of the basis for knowledge, who was involved, how they were involved, or explanation of the scheme itself, "[e]mployees of PHS, HMC's corporate parent, were aware of this scheme . . .").

ARGUMENT

I. RELATOR FAILS TO PLEAD AN FCA CLAIM WITH SPECIFICITY (FRCP 9(B)).

To establish a cause of action under the FCA, a plaintiff must plead: "(1) a false statement or fraudulent course of conduct; (2) that was made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money (i.e., that involved a claim)." *U.S. ex rel. Spicer v. Westbrook*, 751 F.3d 354, 365 (5th Cir. 2014). Rule 9(b) establishes a high bar for pleading, and at a minimum "requires allegations of the particulars of time, place, and contents of the false representations, as well as the identity of the person making the representation and what the person obtained thereby. . . . Put simply, Rule 9(b) requires the 'who, what, when, where, and how' of the fraud." *U.S. v. Emergency Staffing Sols., Inc.*, No. 3:19-CV-1238-E, 2023 WL 2754347, at *4 (N.D. Tex. Mar. 31, 2023) (citations omitted). The Anti-Kickback Statute and Stark Law can in certain circumstances serve as a basis for an FCA claim, s*ee U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 900 (5th Cir. 1997),

but Relator has failed to state an FCA claim based on violations of the AKS or Stark Law.

A. Prime Healthcare Services, Inc. should be dismissed.

Relator has not alleged any wrongful conduct on the part of PHSI but attempts to lump it in with HMC. More is required to implicate a defendant in an FCA action. A complaint alleging FCA violations must satisfy the requirements of Rule 9(b) "as to *each* Defendant, and it is 'impermissible to make general allegations that lump all defendants together.'" *U.S. ex rel. Frey v. Health Mgmt. Sys., Inc.*, No. 4:21-CV-02024, 2023 WL 2563239, at *7 (S.D. Tex. Feb. 10, 2023), *report and recommendation adopted*, No. 4:21-CV-02024, 2023 WL 2564342 (S.D. Tex. Mar. 17, 2023) (citation omitted). "A bedrock principle of corporate law is that 'a parent corporation . . . is not liable' for actions taken by its subsidiaries." *Bridas S.A.P.I.C. v. Gov't of Turkmenistan*, 447 F.3d 411, 416 (5th Cir. 2006) (quoting *U.S. v. Bestfoods*, 524 U.S. 51, 61 (1998)); *see also Al Rushaid v. Nat'l Oilwell Varco, Inc.*, 757 F.3d 416, 423 (5th Cir. 2014) ("Imputing to a party the actions of its codefendants merely on the ground that the entities are jointly owned or controlled or share representation would contravene the fundamental principle of corporate separateness."). "It has been established that merely being a parent corporation of a subsidiary that commits a FCA violation, without some degree of participation by the parent in the claims process, is not enough to support a claim against the parent for the subsidiary's FCA violation." *U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 59-60 (D.D.C. 2007) (internal citation omitted).

Relator's *only* allegation as to PHSI with any specificity is that it is the General Partner of HMC. *See* FAC ¶ 10. There are only two paragraphs in the entire FAC discussing PHSI alone: the allegation about ownership (¶ 10) and an assertion that employees of PHSI were aware of the scheme but took no action because PHSI was profiting from the surgeries (¶ 54). This conclusory allegation about knowledge of the "scheme" is backed up by no detail to make this allegation

plausible and is a far cry from satisfying the particularity strictures of Rule 9(b). Not a single PHSI representative is identified, nor is there any description of what PHSI learned when, or how it "was profiting" from surgeries described in the FAC. Elsewhere, PHSI is indistinguishably linked with HMC, Dr. Six and Mr. Gonzales or the "Defendants" in claiming PHSI knowledge of Dr. Six's relationship with Mr. Gonzales and Mr. Gonzales's relationships with NuERA and Xspine/Xtant. FAC ¶¶ 50 & 60-64. Finally, the same undifferentiated pleading is found in the allegations lumping PHSI in with other Defendants in alleging a conspiracy. *Id*. ¶ 69.

The FAC likewise fails to plead knowledge with regard to PHSI. The FAC concludes that PHSI knew that Mr. Gonzales is Dr. Six's son-in-law and then skips to the conclusion that the relationship constituted a Stark Law violation. *Id.* ¶ 56. The FAC alleges "employees of PHS . . . were aware of this scheme[,]" but do not name any employees, recount any conversations or meetings, describe the source of any knowledge, or describe what aspects of the so-called "scheme" these unidentified individuals had knowledge of. *Id.* ¶ 54. With regard to PHSI, the FAC offers only conclusions and provides "no indicia of any actual knowledge of any FCA-violating fraud." *Nunnally*, 519 Fed. App'x at 893.

At bottom, Relator's theory seems to be that PHSI is a general partner of HMC, so all allegations as to one must apply to the other. This completely disregards key tenets of corporate and partnership law. *See U. S. ex rel. Lewis v. Cmty. Health Sys., Inc.*, No. 18-20394-CIV, 2020 WL 3103994, at *19 (S.D. Fla. June 11, 2020) (concluding that a holding company cannot be "held liable merely by virtue of its status as an owner, director or indirect, of the Managing Company and the Hospitals"); *U. S. ex rel. Heller v. Guardian Pharmacy*, LLC, 521 F. Supp. 3d 1254, 1280-81 (N.D. Ga. 2021) (dismissing parent company where "at best" the relator's allegations demonstrate that parent company "owns a significant portion of subsidiary and controls its macro-

level operations, which are implemented at the local level by a separate team"). Accordingly, all claims against PHSI should be dismissed.

B. No claim is pled with specificity nor is any "reliable indicia" pled.

To survive a motion to dismiss, a complaint must allege either "the details of an *actually submitted false claim*" or "*particular details of a scheme* to submit false claims *paired with reliable indicia* that lead to a strong inference that the claims were actually submitted." *Grubbs*, 565 F.3d at 190 (emphasis added). Relator has done neither. It is indisputable that the FAC fails to plead the actual details of any false claim submitted to a federal healthcare program. In the absence of this, *Grubbs* provides an example of the "particular details" and "reliable indicia" required to survive 9(b). In *Grubbs*, the Fifth Circuit reversed dismissal of a complaint for insufficient pleading when the complaint "set[] out the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud" and the relator "describe[d] in detail, including the date, place, and participants, the dinner meeting at which two doctors . . . attempted to bring him into the fold of their on-going plot" and the relator's "first-hand experience of the scheme unfolding as it related to him, describing how the weekend on-call nursing staff attempted to assist him in recording face-to-face physician visits that had not occurred," and listed specified services that were not provided, and the dates on which they were recorded. 565 F.3d at 191-92. The Fifth Circuit concluded that in light of this volume of evidence, it "would stretch the imagination" to say that fraudulent claims were not submitted to the Government. *Id*. at 190-91. In comparison to the facts alleged in *Grubbs*, Relator's Complaint leaves much to the imagination.

Relator pleads no claim actually submitted to federal healthcare programs and no detail about billing supporting an inference that claims were submitted. The FAC makes the conclusory statement that "every bill . . . submitted to the USG or TSG" was a Stark Law and Anti-Kickback violation but does not plead the details of a single claim submitted to the United States or State of

Texas. FAC ¶¶ 53, 58. Moreover, the Complaint fails to add any reliable indicia about the fraudulent scheme such as any details about the time, place, participants, and particular workings of any billing department, claims rendered to patients as a result of the scheme, or the claims submission practices of Defendants. The Complaint also makes no specific reference to any date relevant to the scheme, such as the date Mr. Gonzalez and Dr. Six became related, the date Mr. Gonzalez became affiliated NuERA and Xtant/Xpine, the date HCM began purchasing spinal equipment from NuERA and Xtant/Xpine, or the date Dr. Six performed any surgery at HCM using NuERA and Xtant/Xpine equipment. *See Nunnally,* 519 F.App'x. at 894 ("[The] complaint fails to allege any particular details . . . or even to offer a time period more distinguishing than 'since approximately 1992 and continuing to date.' The complaint merely states that 'relator estimates that during [the] past six years [the defendant] has submitted thousands of such overstated claims . . . ") (cleaned up).

Instead, the FAC alleges broadly that the scheme has occurred over the last decade and merely lists the general requirements for submitting claims to Medicare, Medicaid, and Tricare, such as the requirement that "claims accurately reflect the services rendered and by whom." *Id.* ¶ 39. The FAC's broad and conclusory language fails to specify the details or reliable indicia regarding the alleged scheme, and is precisely the type of "baseless claims" used "as a pretext to gain access to a 'fishing expedition'" that the Fifth Circuit warned about when it described the purpose of Rule 9(b). *Grubbs*, 565 F.3d at 190-91. Under the Fifth Circuit standard in *Grubbs*, Relator has failed to plead a violation of the FCA, and the Court should dismiss the Complaint.

II. RELATOR FAILS TO STATE AN FCA CLAIM BASED ON THE STARK LAW (FRCP 12(B)(6)).

The Stark law "prohibits physicians from referring Medicare patients to an entity [such as a hospital] for certain 'designated health services' including inpatient and outpatient hospital

services, if the referring physician has a nonexempt 'financial relationship' with such entity." *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997) (quoting 42 U.S.C. § 1395nn(a)(1), (h)(6)) (explanatory bracket added). Distilled to its essence, a Rule 12(b)(6) analysis under the Stark Law proceeds as follows:

Step 1: Are the following elements met?:

1) Physician;

2) making referrals;

3) of Medicare patients;

4) to an "entity" (e.g., a hospital);

5) for Designated Health Services (e.g., inpatient and outpatient hospital services); and

6) a direct or indirect "financial relationship" exists between physician (including an "immediate family member") and the entity.

Step 2: Does a relevant exception apply?

See generally 42 U.S.C. § 1395nn; 42 CFR § 411.353. If Step 1 is not met, the claim fails as a matter of law and there is no need to consider the exceptions.

If the prima facie elements are established and no exception applies, the entity cannot present a claim to Medicare pursuant to a referral from a physician with whom it has a financial relationship. 42 U.S.C. § 1395nn(a)(1)(B); 42 CFR § 411.353.

A. <u>Relator fails to plead prima facie Stark Law elements with particularity</u>.

Relator has failed to plead the majority of the Stark Law's prima facie elements. In fact, the Complaint successfully pleads only two elements 1) that Eric Six is a **physician** (FAC ¶ 5), and 2) HMC is a hospital that qualifies as an **entity** under Stark (*Id.* ¶ 9). *See* 42 CFR § 411.351

(defining entity and physician). Relator attempts to allege a "financial relationship" between HMC and NuERA or Xspine/Xtant, which in some unspecified manner one is left to assume passes a financial benefit to Michael Gonzales, who became Dr. Six's son-in-law at an unspecified time. The Stark Law considers prohibited referrals to include immediate family members of a physician, including a son-in-law, when there is a direct or indirect financial relationship between the immediate family member and the hospital. *See* 42 CFR §§ 411.351; 411.353(a). But for the reasons explained below, Relator's allegations regarding NuERA and Xspine/Xtant are insufficient to establish a Stark Law-regulated financial relationship.

Moreover, the balance of the prima facie elements are pled with no detail. As discussed above, the FAC pleads no specificity as to a single **referral** of a **Medicare patient** from Dr. Six to HMC for **Designated Health Services ("DHS")**. Rather, the Complaint speaks in generalities of Dr. Six performing spine surgeries at HMC, but there are no details of the types of procedures, which patients, with what medical devices. FAC ¶¶ 5, 46-48, 57. Most critically, there is no allegation with any detail that Dr. Six referred a Medicare patient to HMC, and the reader is even left to interpret the type of DHS potentially implicated—inpatient hospital services. *See* 42 CFR § 411.351 (definition of DHS). The best Relator can muster is conclusory references to Medicare claims. *See* FAC ¶¶ 66, 75, 81.

B. Relator pleads no Stark-regulated "financial relationship."

Relator fails to plead the existence of a financial relationship between HMC and Mr. Gonzales.[2] A "financial relationship" under the Stark Law can either be a direct or indirect compensation arrangement or an "ownership or investment interest." 42 U.S.C. § 1395nn(a)(2);

[2] Relator does not allege any compensation being paid from HMC to Dr. Six. Therefore, the evaluation of whether a direct or indirect financial relationship exists is only relevant between HMC and Mr. Gonzales.

42 CFR § 411.354. Here, Relator alleges no "ownership or investment interest" by Mr. Gonzales or Dr. Six in HMC. The FAC appears instead to attempt to plead a compensation arrangement. But, relator does not plead a direct compensation arrangement—i.e., a direct flow of compensation from HMC to Dr. Six or Mr. Gonzales. *Id.* at § 411.354(a)(2)(i).[3] Instead, the Complaint attempts to plead an indirect compensation arrangement by alleging that payments move from HMC to third-party companies NuERA or Xspine/Xtant before they pass to Michael Gonzales. FAC ¶ 64. However, the Stark Law imposes additional pleading obligations with respect to an indirect compensation arrangement under 42 C.F.R. § 411.354(c)(2), which Relator cannot satisfy.

To meet the definition of an indirect compensation arrangement—as required by the alleged scheme outlined in this case—Relator must establish, "(1) there exists an ***unbroken chain*** of any number of persons or entities that have financial relationships between them; (2) the referring physician receives ***aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated*** by the referring physician for the entity furnishing the designated health services, and (3) the entity has knowledge that the compensation so varies." *U.S. v. Cath. Health Initiatives*, No. 4:18-CV-123, 2022 WL 2657131, at *6 (S.D. Tex. Mar. 31, 2022), *report and recommendation adopted sub nom. Chihi v. Cath. Health Initiatives*, No. 4:18-CV-00123, 2022 WL 2652135 (S.D. Tex. July 8, 2022) (citations omitted and emphasis added). More specifically, a plaintiff "must allege the entity 'has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician . . . receives aggregate compensation that varies with the volume or value of referrals or other business

[3] To allege a direct compensation relationship, Relator would have to show that compensation passes directly between the referring physician, or immediate family member, and the entity furnishing the medical service without any intervening person or entity. 42 C.F.R. § 411.354(c)(1)(i).

generated by the referring physician.'" *Id.*[4] Courts have granted motions to dismiss for failure to plead the elements of the indirect compensation definition. *See id.* Relator bears the prima facie burden on each of these elements, without which Relator's claim cannot proceed.[5]

HMC and PHSI do not challenge the sufficiency of pleading the first element—an unbroken chain of financial relationships from HMC to NuERA (or Xspine/Xtant) to Michael Gonzales. However, the second and third elements are not pled with specificity, or for that matter at all. In this case, the second element asks whether aggregate compensation to Mr. Gonzales varies with, or takes into account, the volume or value of referrals made by Dr. Six. Here, the relevant question is the payment relationship between Mr. Gonzales and Xspine/Xtant (as Mr. Gonzales takes the place of the referring physician because he is the immediate family member of the physician) or between NuEra and HMC (because Mr. Gonzales has an alleged ownership interest in NuEra).[6] No detail is pled about either of these payments. The Complaint pleads no

---

[4] Relator's lack of precision as to facts and timing underscores why Rule 9(b) exists to put the defendant on notice of the allegations. This is highlighted in the context of the indirect compensation definition, which has been revised twice in recent years, such that different text governs different time periods (prior to January 19, 2021; from Jan. 19, 2021 to Dec. 31, 2021; and from January 1, 2022 to present). *See* Appendix A for a comparison of how the language has changed. *Cath. Health Initiatives*, 2022 WL 2657131, refers to the operative version before January 19, 2021. The result, however, remains the same under all revisions of the definition, as Relator's FAC pleads no detail of any of the revised definitional elements other than the unbroken chain of financial relationships.

[5] This gating definitional section of "indirect compensation" should not be confused with the separate Stark Law exception for indirect compensation found at 42 C.F.R. § 411.357(p).

[6] If the financial relationship between the referring physician (in this case, Mr. Gonzales due to the "immediate family member" definition) and the person or entity with which the referring physician (Mr. Gonzales) has a direct financial relationship (i.e., NuERA or Xspine/Xtant) is an ownership or investment interest, the determination of whether the aggregate compensation varies with or takes into account the volume or value of referrals or other business generated will be measured by the non-ownership/investment interest closest to the referring physician. 42 C.F.R. § 411.354(c)(2)(ii). For example, if the referring physician owns Company A, which owns Company B, which has a compensation arrangement with Company C, which has a compensation

detail about the financial relationship between NuERA and Mr. Gonzales other than a vague statement about ownership, and most relevant for this analysis it pleads no detail of how the agreement between NuERA and HMC is structured. FAC ¶¶ 7, 61. It further pleads no detail about the financial relationship between Xspine/Xtant and Mr. Gonzales other than "commissions." FAC ¶ 64. Relator has not pled any detail about how and to what extent Mr. Gonzales is compensated for medical devices that are purchased through these companies. No detail is pled that payments to Mr. Gonzalez under this arrangement or any payment from HMC to NuERA "varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician," so the second element fails. The FAC similarly pleads no detail of any knowledge or reckless disregard on the part of the HMC or PHSI, that the aggregate compensation to Mr. Gonzales varies with the volume of referrals or HMC business generated by Dr. Six. *See e.g. Cath. Health Initiatives*, 2022 WL 2657131 at *6 (holding that a Stark allegation was not pled where the relator did not plead that the the hospital defendant knew there was a connection between the volume or value of referrals it received from certain physicians and the amount of indirect compensation those physicians received through a different related hospital). Thus, the third element also fails. In sum, the allegations in the FAC do not satisfy the elements of an indirect compensation arrangement, meaning the Stark Law does not apply to this conduct. Relator's claims premised on a Stark Law violation should be dismissed.

III. RELATOR FAILS TO STATE AN FCA CLAIM BASED ON THE ANTI-KICKBACK STATUTE (FRCP 12(B)(6)).

To state an FCA claim based on the AKS, Relator must plead that a healthcare provider 1)

---

arrangement with Company D, which is a DHS Entity, one would look to the aggregate compensation between Company B and Company C. *Id*.

knowingly and willfully 2) offered, paid, solicited, or received remuneration 3) in return for referring an individual for federally funded medical services. 42 U.S.C. § 1320a-7b(b). Relator must "sketch how it was that Defendant provided remuneration to its clients, the form of that remuneration, how and why Defendant believed that remuneration would induce new business, and how Defendant benefited from the remuneration." *U.S. ex rel. Ruscher v. Omnicare, Inc.*, No. 4:08-CV-3396, 2014 WL 2618158, at *10 (S.D. Tex. June 12, 2014), *on reconsideration in part sub nom. Ruscher v. Omnicare Inc.*, No. 4:08-CV-3396, 2014 WL 4388726 (S.D. Tex. Sept. 5, 2014).

Here, the FAC fails to make any showing of *remuneration*. Relator alleges that HMC and Dr. Six had a "scheme of mutual exploitation" through which HMC paid Dr. Six's son in-law Michael Gonzales through intermediate entities for medical devices when Dr. Six performed surgeries at HMC. FAC ¶ 56. In fact, all that is pled is that HMC purchased medical devices. Relator fails to allege that HMC in any way paid for medical devices that were unnecessary or that HMC paid above fair market value for the devices from NuERA and Xspine/Xtant. The FAC alleges no detail of what remuneration passed from HMC to Michael Gonzales through NuERA and Xspine/Xtant. It is also significant that the Complaint pleads no allegation of remuneration passing from Mr. Gonzales to Dr. Six. Indeed, Relator appears to conflate the Stark Law's explicit treatment of a physician's immediate family members as relevant for purposes of determining the presence of a financial relationship. *See infra.* However, the AKS contains no such rule. Under the AKS, the remuneration must be provided to Dr. Six, but, no detail is pled of any remuneration passing from HMC to Dr. Six—whether directly or through Mr. Gonzales.

Along with the lack of remuneration, the Complaint fails to allege that HMC actually induced the referral of any federal healthcare program patient. *See U.S. ex rel. Nunnally v. W.*

Calcasieu Cameron Hosp., 519 Fed. App'x 890, 894 (5th Cir. 2013) ("actual inducement is an element of the AKS violation . . . and [the plaintiff] must provide reliable indicia that there was a kickback provided in turn for the referral of patients. This requires pleading that [the defendant] knowingly paid remuneration to specific physicians in exchange for referrals."); 42 U.S.C. § 1320a-7b(b)(2). No agreement, discussion, or event is alleged in the FAC about any kick-back tainted understanding between HMC and Dr. Six. All that remains are "sweeping and conclusory allegations." *Nunnally*, 519 Fed. App'x at 894. Taking all that Relator alleges as true, the FAC lacks the "details of a scheme" and lacks "reliable indicia that lead to a strong inference" that any false claims were submitted by way of an AKS violation. *U.S. v. Cath. Health Initiatives*, 312 F. Supp. 3d 584, 598 (S.D. Tex. 2018), *aff'd sub nom*. *U.S. ex rel. Patel v. Cath. Health Initiatives*, 792 F. App'x 296 (5th Cir. 2019).

The FAC fails to allege HMC offered or paid any improper remuneration and that any remuneration led to the inducement of any referral. Relator's AKS theory should be properly dismissed pursuant to Rule 12(b)(6).

IV. RELATOR FAILS TO STATE A CONSPIRACY CLAIM UNDER THE FCA (FRCP 12(B)(6)).

The FCA, 31 USC § 3729(a)(1)(C), prohibits any person from "conspir[ing] to defraud the Government by getting a false or fraudulent claim allowed or paid." To prove an FCA conspiracy, a plaintiff must show "(1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid by [the Government] and (2) at least one act performed in furtherance of that agreement." *Grubbs*, 565 F.3d at 195. The heightened pleading requirements of Rule 9(b) apply as well to the FCA conspiracy provision. *Id.* To plead an FCA conspiracy, a plaintiff must "plead with particularity the conspiracy as well as the overt acts . . . taken in furtherance of the conspiracy." *Id.* (quoting *FC Inv. Group LC v. IFX Markets, Ltd.*, 529 F.3d

1087, 1097 (D.C. Cir. 2008).

The FAC includes only threadbare allegations such as "Defendants were all aware of each other's activities and coordinated their efforts in a seamless course of conduct that persisted for the greater part of a decade." FAC ¶ 69. This allegation fails to plead any detail of "an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid" by the government. *Grubbs*, 565 F.3d at 195. There must be a meeting of minds between defendants for a conspiracy, but Relator does not identify which minds are alleged to have met. Other than undifferentiated references to "Defendants," Relator does not identify which of the defendants are alleged to have participated in any conspiracy. Relator does not specify who allegedly conspired with whom or how.

Relator also fails to plead with particularity the second element of an FCA conspiracy claim, "at least one act performed in furtherance of [an unlawful] agreement." *Grubbs*, 565 F.3d at 195. Relator again offers conclusory summaries: "[t]hrough the acts described above, Defendants entered one or more conspiracies" and "took substantial steps in furtherance of those conspiracies." FAC ¶¶ 81, 93. The "steps" in furtherance of a conspiracy, Relator alleges, were "preparing false records and claims and submitting such documents" to the government. *Id.* ¶¶ 81, 93. No explanation or details are given for what those "false records" are, who prepared them, or whether any records were even submitted to any federal healthcare program. Accordingly, Relator has not pled any fact to illustrate even one specific "act performed in furtherance of" any unlawful agreement. *Grubbs*, 565 F.3d at 195. Relator's conspiracy claims should be dismissed.

V. RELATOR FAILS TO STATE A CLAIM UNDER THE TMFPA (FRCP 12(B)(6)).

Relator alleges violations of three subsections of the Texas Medicaid Fraud Prevention Act ("TMFPA"), which serves as an enforcement mechanism for ensuring the integrity of the Texas Medicaid Program. *In re Xerox Corp.*, 555 S.W.3d 518, 525 (Tex. 2018). First, Relator attempts

to plead a violation of § 36.002(4)(B), which prohibits knowingly making a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law pertaining to the state Medicaid program. This allegation is predicated on an underlying violation of the AKS or Stark Law, and it fails to state a claim for the reasons outlined above.

Next, Relator attempts to plead a violation of § 36.002(5), which prohibits knowingly charging or receiving "in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program." The FAC lacks any factual allegation that HMC or PHSI paid "a gift, money, a donation, or other consideration" for any service or equipment beyond that of its fair market value. Moreover, the FAC did not allege that any specific claims were even submitted to Medicaid; the FAC made only a general conclusion that false claims were submitted "via the Medicare, Medicaid, and TriCare system for payment or approval." FAC ¶ 81.

Finally, Relator's attempts to allege a violation of § 36.002(9), which prohibits conspiring to violate the previously stated subsections. Given the lack of facts to support violation of the previous subsections or provide any factual allegations of overt acts, this claim also fails to satisfy the plausibility requirement for pleading under Rule 9(b).

VI. RELATOR SHOULD NOT BE GRANTED LEAVE TO AMEND.

The Complaint should be dismissed with prejudice. Rule 15(a) instructs courts to give leave to amend "freely," but leave to amend is not automatic. Leave to amend is not appropriate where the putative amendment would be futile or cause undue prejudice to the opposing party, or when a party has repeatedly failed to cure deficiencies by amendments previously allowed. Relator has already amended his complaint once and added no pleading detail that changes the outcome of this question. Futility is present here, as Relator does not plead any first-hand knowledge and

is unlikely to make a better showing on repleading. There is no reason to believe Relator possesses the factual knowledge to satisfy the elements of the alleged causes of action or that has access to insider information to supplement his allegation. Relator will not be able to cure the deficiencies described herein.

RELIEF SOUGHT

Harlingen Medical Center, L.P. and Prime Healthcare Services, Inc. move this Court to dismiss Realtor's Complaint with prejudice.

Respectfully Submitted,

/s/ Edward Michael Rodriguez
Edward Michael Rodriguez
Atlas Hall & Rodriguez LLP
222 N. Expressway 77
Ste 203
Brownsville, TX 78521
956-574-9333
Fax: 956-574-9337
Email: mrodriguez@atlashall.com

/s/ Michael E. Paulhus
Michael E. Paulhus (pro hac vice)
Stephanie F. Johnson (pro hac vice)
King & Spalding, LLP
1180 Peachtree Street NE, Suite 1600
Atlanta, GA 30309
(404) 572-4600
Email: mpaulhus@kslaw.com
Email: sfjohnson@kslaw.com

Attorneys for Defendants Harlingen Medical Center L.P. and Prime Healthcare Services, Inc.

APPENDIX A

Stark Regulations: Indirect Compensation Arrangement ("ICA") Definition (42 C.F.R. § 411.354(c)(2))		
A Stark-regulated indirect compensation arrangement exists if –		
Prior to Jan. 19, 2021:	**From Jan. 19, 2021 to Dec. 31, 2021:**	**Beginning Jan. 1, 2022:**
Between the referring physician (or immediate family member) and the entity furnishing DHS ("DHS Entity"), there exists an unbroken chain of any number of persons or entities (but not fewer than one) that have financial relationships between them; and The referring physician receives aggregate compensation from the person or entity in the chain with which the referring physician has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the DHS Entity, regardless of whether the individual unit of compensation satisfies the special rules on unit compensation set forth at 42 C.F.R. § 411.354(d)(2) and (d)(3);[i] and The DHS Entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the DHS Entity.	Between the referring physician and the DHS Entity there exists an unbroken chain of any number of persons or entities (but not fewer than one) that have financial relationships between them; and The referring physician receives aggregate compensation from the person or entity in the chain with which the referring physician has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the DHS Entity[ii] and the individual unit of compensation received by the referring physician – • Is not fair market value for items and services actually provided; • Includes the physician's referrals to the DHS Entity as a variable, resulting in an increase or decrease in the physician's compensation that positively correlates with the number or value of the physician's referrals to the entity;[iii] or • Includes other business generated by the physician for the DHS Entity as a variable, resulting in an increase or decrease in the physician's compensation that positively correlates with the number or value of the physician's referrals to the entity; and	Between the referring physician and the DHS Entity there exists an unbroken chain of any number of persons or entities (but not fewer than one) that have financial relationships between them; and The referring physician receives aggregate compensation from the person or entity in the chain with which the referring physician has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the DHS Entity;[iv] and The amount of compensation that the physician receives per individual unit[v] – • Is not fair market value for items and services actually provided; • Could increase as the number or value of the physician's referrals to the DHS Entity increases, or could decrease as the number or value of the physician's referrals to the DHS Entity decreases; • Could increase as the amount or value of the other business generated by the physician for the DHS Entity increases, or could decrease as the amount or value of the other business generated by the physician for the DHS Entity decreases; or

	• The DHS Entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the DHS Entity.	• Is payment for the lease of office space or equipment or for the use of premises or equipment; and The DHS Entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the DHS Entity.

[i] If the financial relationship between the referring physician and the person or entity with which the referring physician has a direct financial relationship is an ownership or investment interest, the determination of whether the aggregate compensation varies with or takes into account the volume or value of referrals or other business generated will be measured by the non-ownership/investment interest closest to the referring physician. 42 C.F.R. § 411.354(c)(2)(ii). For example, if the referring physician owns Company A, which owns Company B, which has a compensation arrangement with Company C, which has a compensation arrangement with Company D, which is a DHS Entity, one would look to the aggregate compensation between Company B and Company C. *Id*.

[ii] If the financial relationship between the referring physician and the person or entity with which the referring physician has a direct financial relationship is an ownership or investment interest, the determination of whether the aggregate compensation varies with the volume or value of referrals or other business generated will be measured by the non-ownership/investment interest closest to the referring physician. 42 C.F.R. § 411.354(c)(2)(ii)(C) (same example as above).

[iii] A positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases. 42 C.F.R. § 411.354(c)(2)(ii)(B).

[iv] If the financial relationship between the referring physician and the person or entity with which the referring physician has a direct financial relationship is an ownership or investment interest, the non-ownership/investment interest closest to the referring physician is used to determine whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the DHS Entity and whether the amount of compensation that the physician receives per individual unit meets the conditions specified above. 42 C.F.R. § 411.354(c)(2)(ii)(C) (same example as above).

[v] The individual unit is (i) item, if the physician is compensated solely per item provided; (ii) service, if the physician is compensated solely per service provided, which includes arrangements where the "service" provided includes both items and services; and (iii) time, if neither of the foregoing provisions is met. 42 C.F.R. § 411.354(c)(2)(ii)(B).